

Application No. 10/044,354  
Reply to Office Action dated August 11, 2004

### Remarks

Applicant has carefully reviewed the Office Action mailed on August 11, 2004. Applicant respectfully traverses all objections, rejections, and assertions made by the Examiner. Claims 1-3, 5-8, 10-20, 23-27, and 29-39 are examined; claims 9, 21, 22, and 28 are withdrawn from consideration.

### Rejection under 35 U.S.C. § 103(a)

Claims 1-8, 10-20, 23-27, 29, and 30-39 are rejected as being unpatentable over Epstein et al. (5,951,589) in view of Dieck et al. (6,425,909). The Examiner acknowledges that Epstein et al. fail to teach a filter element attached to the catheter shaft, but asserts that it would have been obvious to modify Epstein's membrane (311) by substituting the filter element taught by Dieck et al. in order to remove plaque and other material that can obstruct blood vessels. Applicant respectfully traverses the rejection.

The entire disclosure of Epstein et al. is directed to an expansile device for percutaneous occlusion of vascular access sites. That is, complete blockage of the vessel rather than filtration where blood continues to flow. See column 1, line 11 through column 2, line 44. The various embodiments that Epstein et al. describe in detail are devices with an impermeable membrane functioning as a closure mechanism. See column 4, lines 13-35. The Epstein et al. reference contains two recitations of a permeable membrane, the first at column 19, lines 26-28, "membrane 311 can also be made of an impermeable or a permeable material providing for multiple uses of the device," and the second at column 20, lines 61-63, "different membrane materials may be utilized in order to construct permeable or impermeable assemblies for different function." Epstein et al. do not, however, provide any indication of to what the membrane could be permeable or what function it would serve if it were permeable. Additionally, Epstein et al. specifically disclose that "the membrane 311 is substantially impermeable to blood and other liquids." See column 19, lines 40-41. Thus, even if the membrane were permeable to some substances, Epstein et al. make it clear that the membrane is to be impermeable to blood and other liquids.

Dieck et al. disclose devices for filtering fluid flowing through a body structure such as a vessel. Applicant submits that one of ordinary skill in the art, upon reading

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Epstein et al. would not be motivated to substitute the filter of Dieck et al. for the occlusion membrane in Epstein's device because doing so would appear to destroy or at least significantly alter the functionality of the Epstein et al. device. MPEP 2143.01 states that if a "proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification," citing *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984). MPEP 2141.03 states that a "prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention," citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983).

Applicant submits that when considered in its entirety, the Epstein et al. reference is directed to a device with an impermeable membrane for occlusion of a puncture site. The fact that Epstein et al. briefly mention that the membrane can be made of permeable or impermeable materials, without providing further guidance regarding an acceptable level of permeability does not detract from the fact that the overall teaching of Epstein et al. is of a device that functions to occlude a puncture site. Additionally, in view of the specific teaching in Epstein et al. that the membrane be substantially impermeable to blood and other liquids, one of ordinary skill in the art might consider gas permeable, yet liquid impermeable membranes could be encompassed by the Epstein et al. device. The scope of the Epstein et al. disclosure is a device with a blood and liquid impermeable membrane that functions to occlude a puncture site. Modifying the Epstein et al. device to have a blood-impermeable membrane would render the device unsuitable for its intended purpose, i.e., stopping blood flow. Furthermore, the Examiner's reason for modifying the Epstein et al. device, that of achieving a device that removes plaque and other material which can obstruct blood vessels, renders the Epstein et al. device unsatisfactory for its intended purpose of occluding a puncture site. Applicant submits that one of ordinary skill in the art would not be motivated to modify the device of Epstein et al. to completely change the function of that device, as suggested by the Examiner.

MPEP 2143.01 further states that if "the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being

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modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious," citing *In re Ratti*, 123 USPQ 349 (CCPA 1959). Applicant submits that substituting the filter of Dieck et al. for the blood-impermeable membrane of Epstein et al. would change the principle of operation of the device taught by Epstein et al., by changing the occlusion device into a filtration device. The principles of operation of the Epstein et al. and Dieck et al. devices are completely opposite, thus modifying the occlusion device to have a filter would render the occlusion device unsuitable for its intended purpose. Applicant submits that there is no motivation, either in Epstein et al., Dieck et al., or reasoned from knowledge generally available to one of ordinary skill in the art, for one to substitute the occlusion membrane of Epstein et al. with the filter of Dieck et al. As such, the only motivation for combining the teachings of Epstein et al. and Dieck et al. appears to come from the instant specification, which is improper. Applicant respectfully requests withdrawal of the rejection.

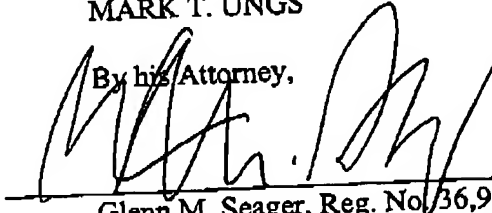
Reexamination and reconsideration are requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is also respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

MARK T. UNGS

By his Attorney,

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